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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,902	12/04/2001	Dale Brown	5369/00015	7185
22910 7590 07/09/2008 BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601				
EXAMINER				
GEMBEHL, SHIRLEY V				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
07/09/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/005,902

**Applicant(s)**

BROWN ET AL.

**Examiner**

SHIRLEY V. GEMBEH

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-25 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 15-25 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/C)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of claims:**

Claims 2-7 and 9-14 have been cancelled and new claims 15-25 are pending.

### **Response to Arguments**

Applicant's argument filed on 3/14/08 in response to the rejection of claims 15-25 under 35 USC 112, first have been fully considered and deemed persuasive, because Applicant has amended the claims to overcome the rejection.

### ***Maintained Claim Rejections - 35 USC § 103***

Applicant argues that Keller does not teach a method to treat periodontal disease which entails the delivery of a medicament in close proximity to the bone and supporting structure of the teeth, and further there is no mention of the term "biofilm"

Applicant also argues that (i) Keller teaches a method to treat periodontal disease which entails the delivery of a medicament in close proximity to the bone and supporting structure of the teeth, and that Keller is not directed to a method of removing biofilm. In fact, the term "biofilm" does not appear in the Keller specification. Instead, Keller teaches a method of treating infection of gum tissue.

(ii) There is nothing in Hill which is directed to soft abrasives and, that the reference teaches a low foaming toothpaste formulation containing an abrasive, a humectant, a surfactant and a foam controlling agent wherein the abrasive/tooth surface interface and abrasive packing is delivered using a channeled bristle toothbrush.

(iii) Kim does not teach the use of the term term biofilm and that the teaching is to a specific extract of *Achyranthis radix* or *Ulmus cortex* as described therein, providing the desired effect of inhibiting the production of the periodontal disease-inducing agents and at the same time inhibiting the activity of the periodontal tissue-decomposing enzyme for periodontal tissues, as well as promoting collagen synthesis.

(iv) at best, the cited prior art teaches merely selected elements of the claimed invention - but the "whole" invention claimed herein is neither taught nor suggested by the combined teachings of the cited art. This is not a *KSR* situation, where a limited number of treatments are available to the skilled artisan, and accordingly, the selection of the specific treatments defined in the claims is clearly not an obvious choice from the prior art. Instead, the claimed invention represents a patentable selection of specific treatments useful for the treatment of severe gingival detachment through specific means for the removal of biofilms.

In response, with regard to the item (i) the Keller reference teaches the self treatment decreases plaque development. As to the argument that the teachings of Keller are to a periodontal disease not to removal of biofilm, plaque is a periodontal disease, if it is not treated plaque will affect the bone. Therefore while self treating plaque (biofilm) via the use of floss and tooth brush; biofilm will be removed also. (This embraces the definition of biofilm, see page 9, last paragraph of the specification).

(ii), Col. 5, lines 60 -67, teaches that one can evaluate the polishing of tooth surfaces without a high level removal or scratching, indicating that abrasiveness does not affect

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the teeth enamel, further the reference teaches sodium bicarbonate (soda) and alumina silicate as the abrasive, agents see col. 6, lines 45-50 and line56-60. As to the term biofilm not specifically disclosed, the Examiner agrees, however the reference teaches plaque.

(iii) Here, Applicant is arguing what is not claimed. The claims recite addition of therapeutic agents to the composition there is no indication as to what therapeutic agent Applicant is referring to. Again note that periodontal disease is taught as plaque.

Plaque is a biofilm.

(iv) As to the alleged statement that the prior art merely teaches selected elements of the claimed invention. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992).

In this case, the combination and why to combine the prior art has been made in the office action of record.

Applicant's arguments have been fully considered but they are not persuasive. See above reasoning. The rejection is maintained and repeated below.

Claims 15-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Keller, US 5,129,824 (824) taken with Hill, US 5,993,784 (784) and Hill et al., US

5,057,309 (309) in view of Kim et al., US, 6,045,800 (800) as in the last office action of record and for the reasons given above.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SHIRLEY V. GEMBEH** whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **MICHAEL HARTLEY** can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

SVG  
6/21/08